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RESEARCH**

*APPLICATION NUMBER:*

**21-543**

**MICROBIOLOGY REVIEW**

# **Product Quality Microbiology Review**

## **Review for HFD-580**

**25 FEBRUARY 2003**

**NDA: 21-543**

### **Drug Product Name**

**Proprietary: Striant™**

**Non-proprietary: testosterone buccal bioadhesive**

**Drug Product Classification: Androgen**

**Review Number: 1**

### **Subject of this Review**

**Submission Date: 7 August 2002**

**Receipt Date: 8 August 2002**

**Consult Date: 3 December 2002**

**Date Assigned for Review: 11 December 2002**

### **Submission History (for amendments only)**

**Date(s) of Previous Submission(s): N/A**

**Date(s) of Previous Micro Review(s): N/A**

### **Applicant/Sponsor**

**Name: Columbia Laboratories**

**Address: 100 North Village Ave., Suite 32; Rockville Centre, NY 11570**

**Representative: Susan Witham, V.P. Reg. Affairs**

**Telephone: 973-994-3999 ext 7907**

**Name of Reviewer: Bryan S. Riley, Ph.D.**

**Conclusion: Recommended for Approval**

## Product Quality Microbiology Data Sheet

- A.
1. TYPE OF SUPPLEMENT: N/A
  2. SUPPLEMENT PROVIDES FOR: N/A
  3. MANUFACTURING SITE: Mipharm S.p.A.  
Via B. Quaranta, 12  
20141 Milan, Italy
  4. DOSAGE FORM, ROUTE OF ADMINISTRATION AND  
STRENGTH/POTENCY: Buccal Bioadhesive, 30 mg
  5. METHOD(S) OF STERILIZATION: N/A
  6. PHARMACOLOGICAL CATEGORY: Androgen
- B. SUPPORTING/RELATED DOCUMENTS: None
- C. REMARKS: The drug product is a solid tablet to be applied to the gums for sustained controlled release of the drug substance.

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**Executive Summary****I. Recommendations**

- A. Recommendation on Approvability** – This submission is recommended for approval on the basis of product quality microbiology.
- B. Recommendations on Phase 4 Commitments and/or Agreements, if Approvable** – N/A

**II. Summary of Microbiology Assessments**

- A. Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology** – The drug product is a non-sterile solid dosage form to be placed on the patient's gum.
- B. Brief Description of Microbiology Deficiencies** - None
- C. Assessment of Risk Due to Microbiology Deficiencies** – The drug product is a solid dosage form. Stability testing during development have demonstrated that the drug product is of appropriate microbial quality and is likely to remain so over time. Therefore, the drug product presents very little risk from the standpoint of product quality microbiology.

**III. Administrative**

- A. Reviewer's Signature** 
- B. Endorsement Block**  
Bryan S. Riley, Ph.D. (Microbiology Reviewer)  
Peter H. Cooney, Ph.D. (Microbiology Supervisor)
- C. CC Block**  
N/A

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/s/

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Bryan Riley  
3/6/03 12:38:09 PM  
MICROBIOLOGIST

Peter Cooney  
3/6/03 01:38:19 PM  
\_\_\_\_ MICROBIOLOGIST